DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 14, 2014

Medtronic Inc.
Ms. Gerardine Finn
VP of Regulatory Affairs – Coronary and RDN
Cardiac & Vascular Group
3576 Unocal Place
Santa Rosa, CA 95403

Re: K141090
Trade/Device Name: NC Euphora Rapid Exchange Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: July 16, 2014
Received: July 18, 2014

Dear Ms. Finn,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141090

Device Name

NC Euphora™ Rapid Exchange Balloon Dilatation Catheter

Indications for Use *(Describe)*

The NC Euphora™ Rapid Exchange Balloon Dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable stents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary per 21 CRF 807.92

Date Prepared:	August 15th, 2014
Applicant:	Medtronic, Inc. Medtronic Ireland Parkmore Business Park West Galway Ireland
Official Correspondent:	Caitriona Regan Senior Regulatory Affairs Specialist Medtronic Ireland Parkmore Business Park West Galway Ireland Phone: (353) 91 708842 Fax: (353) 91 708672 Email: caitriona.regan@medtronic.com
Proprietary Name:	NC Euphora™ Rapid Exchange Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Device Classification:	Class II (special controls)
Regulation Number:	21 CFR 870.5100
Classification Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Product Code:	LOX

Device Description:	The NC Euphora™ RX Balloon Dilatation catheter is a Percutaneous Transluminal Coronary Angioplasty (PTCA) Rapid Exchange System. The balloon at the distal end of the catheter can be inflated to a defined diameter at a specific pressure as defined in the product labelling. The proximal end of the catheter has a female luer for attachment to an inflation device. The catheter provides a lumen which enables the use of a guidewire to position the catheter. Radiopaque balloon marker bands enable accurate placement. Shaft markers for brachial and femoral techniques are in place. The NC Euphora device is available in balloon diameters of 2.0mm to 5.0mm and in balloon lengths of 6mm to 27mm. The NC Euphora device has a nominal pressure of 12atm and a rated burst pressure of 20atm.
Indications For Use:	The NC Euphora™ RX Balloon Dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable stents.
Substantially Equivalent Device:	The NC Euphora™ RX Balloon Dilatation Catheter is similar to the following predicate device with respect to intended use, design and technology: • Medtronic NC Sprinter® RX Balloon Dilatation Catheter (P790017/S095, approved October 10, 2008)
Summary of Technological Differences to the Predicate Device:	The Euphora™ RX Balloon Dilatation Catheter represents a series of incremental performance improvements over its predicate device NC Sprinter® RX Balloon Dilatation Catheter, with primary attributes including lower balloon radial growth and higher nominal and rated burst pressure. The NC Euphora catheter is also offered in more balloon sizes compared to its predicate and the 2.0mm diameter size is indicated for post deployment expansion of balloon expandable stents.

Summary of Non-Clinical Data:

Design Verification in-vitro testing:

The following in-vitro bench tests were completed on the NC Euphora™ RX Balloon Dilatation Catheter in accordance with the requirements of *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010* and verify that it meets the required performance specifications:

- Effective length
- Catheter Profile
- System Pressure Capability & System Pressure Capability (in Stent)
- Balloon Fatigue & Balloon Fatigue (in Stent)
- Balloon Compliance
- Balloon Inflation and Deflation Time
- Catheter Bond Strength
- Coating Integrity
- Coating Particulate Evaluation
- Flexibility and Kink
- Torque Strength

Pre-Clinical Study (non-GLP):

Medtronic Ireland conducted pre-clinical in-vivo (non-GLP) studies for evaluation of the Radiopacity attribute of the NC Euphora™ RX Balloon Dilatation Catheter.

Biocompatibility Testing:

Biocompatibility testing for the NC Euphora™ RX Balloon Dilatation Catheter has been completed in accordance with the recommendations of *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010* and International Standard ISO10993-1:2009, *Biological Evaluation of Medical devices- Part 1: Evaluation and Testing* for an external communicating device with limited exposure i.e. whose contact with circulating blood is ≤ 24 hours.

The following Biocompatibility tests were performed to support the NC Euphora™ RX Balloon Dilatation Catheter:

- Cytotoxicity Study using ISO MEM Elution method
- ISO Maximisation Sensitisation Study
- ISO Acute Intracutaneous Reactivity
- ISO Acute Systemic Toxicity
- USP Material Mediated Pyrogen Study in Rabbits
- In Vivo Thromboresistance Study
- ASTM In-vitro Haemolysis
- ASTM Partial Thromboplastin Time (PTT) Coagulation Testing
- C3a Complement Activation Assay Study
- Sc5b-9 Complement Activation Assay Study
- USP Physicochemical Tests

The NC Euphora™ RX Balloon Dilatation Catheter met all specified design and performance requirements. No new safety or effectiveness issues were raised during the testing. The bench testing qualification and biocompatibility testing demonstrated that the subject device NC Euphora™ RX Balloon Dilatation Catheter is substantially equivalent in terms of safety and effectiveness to the predicate device.

Summary of Clinical Data: No clinical investigation has been performed for this device.

Sterilization Validation: The NC Euphora™ RX Balloon Dilatation Catheter will be sterilized and validated for E-beam sterilization in accordance with ISO11137, EN556 and TIR33 to achieve a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Conclusion: Through the data and information presented, Medtronic Ireland considers the NC Euphora™ RX Balloon Dilatation Catheter to be substantially equivalent to the predicate device.